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REMARKS

In paragraph 2 of the Office Action, claims 1, 6, 13, 23 and 25-30 were rejected under 35 U.S.C.§103(a) as being unpatentable over Sparks et al. (Sparks).

Reconsideration is requested.

The Sparks patent is limited to the disclosure of a microparticle contaiuning phannaceutical formulation which is made by dissolving or dispersing a polymer and a drug in a solvent and thereafter removing the solvent to obtain microparticles. The microparticles are described as being useful for making a controlled release powder for use in making liquid or solid pharmaceutical dosage forms(col. 1, lines 50-65). The dimensions of the microparticles are 0.1μm to 125μm or 100nm to 125,000nm and preferably 5μm to 100μm or 5,000nm to 100,000nm. The present claims require the use of microparticles in the range of 100-900nm (claim 1) or 200nm to 400nm (claim 30) which is a much narrower range that the range of the Sparks patent. The microparticles of Example 1 of Sparks have a particle size range of 10μ to 180μm or 10,000nm to 180,000nm. This does not suggest the making of a microparticle based effervescent composition having a range of sizes of 100-900nm.

Attached hereto is a Declaration of Dr. Federico Stroppolo who reports on the results of comparative testing of two groups of particles. One group of particles was sized between 200 and 400 micrometers while the second group of particles was sized between 1000 and 1400 micrometers. The test results show that the time required for particles sized from 200 to 400 micrometers to drop to the bottom of a vessel filled with 200ml of water was 60 seconds while the time required for particles sized from 1000 to 1400 was less than one second. When this data is evaluated in view of the disclosure of the Sparks patent, it is apparent that while the ranges claimed in the present application may overlap, the results of the tests of particles of 200 to 400 micrometers could not be predicted based on the Sparks patent.

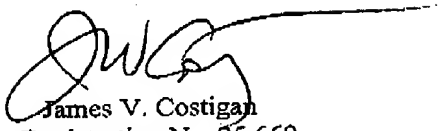
An actual effervescent composition is not described in the Sparks patent. The only mention of an effervescent composition is an effervescent tablet which contains no information as to how the effervescent tablet should be formulated. Claims 1 and 23 both

point out that the claimed formulation is adapted to disperse in water to form an effervescent drink. There is no mention in Sparks of forming an effervescent drink. At col. 7, line 56-59, the resistance of the microparticles to chewing action is noted which suggests that all of the tablets are to be placed in the mouth. This observation is confirmed by the text of Sparks at col. 8, lines 29-32 where Sparks notes that the microparticulate nature of the Sparks formulation provides a good mouth feel for chewable and effervescent tablets due to the absence of a granular sensation. Thus, the thrust of the Sparks patent is away from an effervescent drink.

The Examiner has commented that it is not necessary that an actual example of a particular product be set forth in a patent in order for that patent to make obvious a particular composition. The applicant does not disagree with the Examiner's statement, as to the necessity that a patent contain a particular Example in order for the patent to teach a particular concept. However, in the present case, it has been established that at 1000 to 1400 micrometers, the particles drop out of suspension almost immediately. For these reasons, it is requested that this ground of rejection be withdrawn.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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